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10/599,166

09/21/2006

Graham David Barrett

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EXAMINER

EASTWOOD, DAVID C

ART UNIT

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3731

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/599,166 | Applicant(s) BARRETT, GRAHAM DAVID | |
| | Examiner DAVID EASTWOOD | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 September 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/11/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on 3/3/2009 is acknowledged.
2. Claim 29 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention group II, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/3/2009.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the hollow tube member with ridges and grooves or protuberances with a mid section with an oval cross section with varying wall thickness and the tapered rod member must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

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of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

1. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

2. The abstract of the disclosure is objected to because the abstract is a repeat of the first independent claim of the disclosure. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 5-8, 10-11, 14, 16-17, and 19-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Maaskamp et al (US 6013046).

Regarding Claim 1-3, 5-8, 10-11, 14, 16-17, and 19-26, Maaskamp discloses a phacoemulsification needle (10) characterized by a rod member (12) arranged for transmission of ultrasonic energy to an ocular substrate to effect emulsification thereof, and a hollow tube member (20) having an inner surface defining a lumen arranged for aspiration of emulsified ocular material, the hollow tube member being disposed about the rod member, the rod member having a distal end and a proximal end and the hollow tube member having a distal end and a proximal end, the rod member is concentric with a central longitudinal axis of the lumen (Figure 3), the rod member is of uniform cross section throughout its length (Figure 3), the rod member (12) is of circular, oval or polygonal shape in cross section (Figure 4), the distal end of the rod member is flat, the rod member has an elongate outer surface which is ridged (Figure 3), the hollow tube member (20, 22, 24, 26) is circular or oval in cross section (figure 4 item 26), the hollow tube member has an outer surface and the outer surface and the inner surface define an annular wall (Figures 3), the annular wall is of uniform thickness throughout (Figure 3

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item 26), the hollow tube member has distal and proximal portions formed of relatively rigid metallic material whilst a mid section of the hollow tube member is formed of relatively flexible plastics material (Column 3 lines 13-20), the hollow tube member has a rubberized exterior or a flexible sleeve applied to an exterior surface thereof to reduce wound leakage (Column 3 lines 61-63), capable of use in bimanual phacoemulsification procedures, the rod member is at least partially hollow, the rod member has a hollow distal end to facilitate aspiration of ocular material, the proximal end of the rod member is hollow to facilitate aspiration of ocular material (figure 4 item 12), the hollow distal and proximal ends of the rod member are broader in cross section than an intermediate portion of the rod member, the proximal end of the rod member is enlarged so as to be compatible with a phacoemulsification hand piece (figure 3 items 12 and 16), the rod member has an intermediate portion which is hollow so that the rod member is hollow throughout (figure 4 item 12), the hollow tube member is arranged to divert aspirated ocular material into the proximal end of the rod member, aspirated ocular material is arranged to be diverted through the rod member and the hollow tube member (figure 4),

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 4, 18 and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maaskamp et al (US 6013046) in view of Murry et al (US 3990452).

Regarding claim 4, 18, and 27, Maaskamp discloses the claimed invention except for the rod member is tapered throughout its length so that the cross section of the proximal end of the rod member is greater than the cross section of the distal end of the rod member and is solid throughout.

However, Murry discloses a solid tapered rod member for use with ultrasonic surgical devices (Figure 7a). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Maaskamp with the tapered rod member as taught by Murry. Doing so would provide a device with varying space between the rod member and the hollow tube member increasing cavitations within the irrigating fluid within the device.

Regarding Claim 28, Maaskamp discloses the claimed invention except for the rod member is solid except at the distal end of the rod member

However, Murry discloses a rod member which is solid except for the distal end (Figure 7c items 97 and 93). It would have been obvious to one of ordinary skill in the

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art at the time of invention to modify the invention of Maaskamp with the ultrasonic tip as taught by Murry. Doing so would provide an ultrasonic tip which would increase cavitation within the distal opening of the tip aiding in the cavitations of irrigation fluid.

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maaskamp et al (US 6013046) in view of Rockley (US 2001/0021819).

Regarding Claim 9, Maaskamp discloses the claimed invention except for the distal and proximal ends of the hollow tube member have a circular cross section whilst a mid section of the hollow tube member has an oval cross section.

However Rockley discloses a flexible hollow tube member which when inserted into a wound has a circular cross-section in vivo and proximally (Figure 4 and 6) but has an oval cross-section in its midsection (Fig. 5 and 7). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Maaskamp with the hollow tube with varying cross-section as taught by Rockley. Doing so would provide a sheath for the ultrasonic member which will conform to the wound shape and prevent wound leakage.

9. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maaskamp et al (US 6013046) in view of Banko (US 6299591).

Regarding Claims 12-13, Maaskamp discloses the claimed invention except for the annular wall has a mid section which is thinner than the thickness of the distal and proximal ends of the hollow tube member, the mid section is thin in a plurality of spaced portions of the annular wall with thicker portions disposed between the thinner portions.

However, Banko discloses a hollow tube member (90) with an accordion style mid-section with thicker (88, 92) and thinner annular (90) wall sections. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Maaskamp with the accordion style hollow tube as taught by Banko. Doing so would provide a device which seals the wound and allows for axial movement of the ultrasonic member without breaking said seal.

10. Claim 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Maaskamp et al (US 6013046) in view of Freeman (US 4808154).

Regarding Claim 15, Maaskamp discloses the claimed invention except for the inner surface of the hollow tube member is provided with ridges, grooves or protuberances to generate turbulence in the lumen in use.

However, Freeman discloses a hollow tube member with protuberances and grooves along the annular wall (Figure 5, 6, and 7). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Maaskamp with the hollow tube with protuberances along its annular wall as taught by Freeman. Doing so would promote turbulence within the hollow tube.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see the references cited page 892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID EASTWOOD whose telephone number is

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(571)270-7135. The examiner can normally be reached on Monday thru Friday 9 a.m. to 5 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID EASTWOOD/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
3/16/09